NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LORY D'ADDARIO and PETER D'ADDARIO, Plaintiffs, v. JOHNSON & JOHNSON; ETHICON, INC.; and MENTOR WORLDWIDE, LLC, Defendants.	Civil Action No. 19-15627 (MAS) (TJB) **MEMORANDUM OPINION**

SHIPP, District Judge

This matter comes before the Court upon Defendants Mentor Worldwide, LLC ("Mentor"), Ethicon, Inc. ("Ethicon"), and Johnson & Johnson's (collectively, "Defendants") Motion to Dismiss. (ECF No. 6.) Plaintiffs Lory D'Addario ("D'Addario") and Peter D'Addario (collectively, "Plaintiffs") opposed (ECF No. 25), and Defendants replied (ECF No. 26).[1] The Court has carefully considered the parties' submissions and decides the matter without oral argument pursuant to Local Civil Rule 78.1. For the reasons set forth below, Defendants' Motion is granted.

[1] Defendants filed a notice of supplemental authority, alerting the Court to three "district court decisions granting Mentor's motions to dismiss in nearly identical cases." (ECF No. 27.) Plaintiffs replied to Defendants' notice. (ECF No. 28.) Thereafter, Defendants filed an additional notice of supplemental authority on another "district court decision granting Mentor's motion to dismiss in a nearly identical case." (ECF No. 29.)

I. BACKGROUND[2]

On June 14, 2013, the United States Food and Drug Administration ("FDA") approved Mentor's premarket approval application for its MemoryShape breast implants (hereinafter, "Mentor Breast Implants"). (Compl. ¶¶ 74, 218, ECF No. 1.) Defendants design, manufacture, market, label, and distribute Mentor Breast Implants. (*Id.* ¶ 1.)

In July 2015, D'Addario underwent breast reconstruction surgery and received Mentor Implants. (*Id.* ¶ 152.) Plaintiffs allege that, at that time, Defendants were aware that Mentor Implants caused breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL") but failed to advise D'Addario of the risk. (*Id.* ¶¶ 73, 153–55.) Had D'Addario known of the slightest risk of BIA-ALCL, she would not have proceeded with the implantation. (*Id.* ¶ 156.)

In July 2017, D'Addario tested positive for BIA-ALCL. (*Id.* ¶ 158.) Following diagnosis and treatment of BIA-ALCL, D'Addario suffered pain, swelling, and embarrassment. (*Id.* ¶ 161.) In August 2017, D'Addario underwent implant removal and total capsulectomy. (*Id.* ¶ 159.) The explantation caused D'Addario tremendous pain. (*Id.* ¶ 160.)

Plaintiffs bring the following Counts against Defendants: (1) Strict Liability—Manufacturing Defect in violation of the Connecticut Product Liability Act ("CPLA"), Con. Gen. Stat. §§ 52-572, *et seq.*; (2) Negligent Misrepresentation; (3) Breach of Express and Implied Warranty; (4) Violation of the Connecticut Unfair Trade Practices Act ("CUTPA"), Conn. Gen. Stat. §§ 42-110b, *et seq.*; and (5) Loss of Consortium. (*Id.* ¶¶ 176–233.)

[2] The Court accepts all well-pleaded factual allegations as true. *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008).

II. LEGAL STANDARD

"Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)) (alteration in original).

District courts undertake a three-part analysis when considering a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). "First, the court must 'tak[e] note of the elements a plaintiff must plead to state a claim.'" *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)) (alteration in original). Second, the court must accept as true all of the plaintiff's well-pled factual allegations and "construe the complaint in the light most favorable to the plaintiff." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (internal quotations and citation omitted). In doing so, the court is free to ignore legal conclusions or factually unsupported accusations that merely state, "the-defendant-unlawfully-harmed-me." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). Finally, the court must determine whether "the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679). "The defendant bears the burden of showing that no claim has been presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005).

III. DISCUSSION

Defendants make the following arguments for the dismissal of Plaintiffs' Complaint: (1) Counts Two through Four are subsumed by the CPLA (Defs.' Moving Br. 10–12); (2) Plaintiffs' product liability claims are preempted by federal law (*id.* at 13–36); (3) Plaintiffs'

claims do not satisfy applicable pleading requirements (*id.* at 36–40); and (4) Plaintiffs' loss of consortium claim fails because it is a derivative claim. The Court addresses each argument in turn.

A. CPLA Subsumption[3]

Defendants argue that Counts Two through Four of the Complaint are subsumed by the CPLA. (*Id.* at 10.) The CPLA provides the exclusive vehicle in Connecticut for actions premised on "harm caused by a product." Conn. Gen. Stat. § 52–572n(a) ("A product liability claim . . . shall be in lieu of all other claims against product sellers, including actions of negligence, strict liability and warranty, for harm caused by a product."). The provision essentially consolidates all product liability claims into a "single form of action." *LaMontagne v. E.I. Du Pont De Nemours & Co.*, 41 F.3d 846, 855 (2d Cir. 1994) (citing *Winslow v. Lewis-Shepard, Inc.*, 562 A.2d 517, 521 (Conn. 1989)).

Here, the Court finds—and Plaintiffs agree (Pls.' Opp'n Br. 34)— that Counts Two and Three alleging negligent misrepresentation and breach of express and implied warranty are subsumed by the CPLA. Although the two claims are dismissed, Plaintiffs may, nonetheless, assert these common law theories of products liability under Count One, their CPLA claim. *Fraser v. Wyeth, Inc.*, 857 F. Supp. 2d 244, 252 (D. Conn. 2012) ("A plaintiff bringing a cause of action

[3] Under New Jersey's "most significant relationship" test, where plaintiffs assert product liability claims, the plaintiffs' home state has the "most significant relationship" to the issues. *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 699 (D.N.J. 2011) (citing *P.V. v. Camp Jaycee*, 962 A.2d 453 (N.J. 2008)). Here, the Court applies the law of Plaintiffs' home state of Connecticut to Plaintiffs' product liability claims, which the parties do not dispute. (Defs.' Moving Br. 7, ECF No. 6; Pls.' Opp'n Br. 5, ECF No. 25.)

under the CPLA therefore retains the right to allege traditional theories of recovery under one unified CPLA claim." (citation omitted)).

Next, the Court turns to Plaintiffs' CUTPA claim. The CPLA will not bar a CUTPA claim if an injury was not caused by a defective product or if the plaintiffs are not pursuing a claim for "personal injury, death or property damage." *Gerrity v. R.J. Reynolds Tobacco Co.*, 818 A.2d 769, 774 (Conn. 2003) (quoting Conn. Gen. Stat. § 52-572m(b)). In other words, where the plaintiffs' CUTPA claim seeks "to redress merely *a financial injury* suffered . . . of a kind that has never been regarded as part of the traditional tort remedy for harm caused by a defective product," the CUTPA claim is not barred. *Id.* at 775.

Plaintiffs' characterization of D'Addario's injuries as "financial" in nature belies their true nature as harms caused by a defective product. (*See* Pls.' Opp'n Br. 23–24.) Plaintiffs allege that, because of Defendants' deceptive trade practices, she suffers from permanent and continuing injuries, which "require medical treatment and hospital expenses" and "lost . . . financial gains." (Compl. ¶ 228.) The Court, however, fails to distinguish between the injuries Plaintiffs allege and those typically asserted in garden-variety products liability suits. The Court, therefore, dismisses Plaintiffs' CUTPA claim as barred by the CPLA's exclusivity provision. For these reasons, the Court dismisses Counts Two, Three, and Four as subsumed by the CPLA.

B. Federal Preemption

Defendants argue that Plaintiffs' state-law claims are either expressly or impliedly preempted by federal law. (Defs.' Moving Br. 13–36.) Defendants also argue that certain claims

fail because Plaintiffs have not alleged parallel state-law duties (*id.* at 28–36) or causal nexuses between her injuries and Defendants' alleged violations (*id.* at 36).

The Medical Device Amendments of 1976 ("MDA") to the Federal Food Drug & Cosmetic Act, 21 U.S.C. §§ 360c, *et seq.*, "imposed a regime of detailed federal oversight" for medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316, 319 (2008). Of the devices regulated under the MDA, Class III devices that undergo the "premarket approval" process receive the greatest oversight. *Id.* at 317. The premarket approval process is "rigorous" and "includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, § 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, § 360e(d)(1)(A)." *Id.* at 317–18.

Premarket approval further imposes "requirements" that are "specific to a medical device." *Id.* at 323–24. Devices are "to be made with almost no deviations from the specifications in its approval application." *Id.* at 323. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319 (citing § 360e(d)(6)(A)(i)).

To determine whether the MDA expressly preempts a state claim under § 360k(a), courts consider (1) whether the FDA has established "requirements" applicable to the specific device at issue; and if so, (2) whether the plaintiffs' claims are based on state requirements that are "different from, or in addition to," the federal ones and that "relate to safety and effectiveness." *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 (3d Cir. 2018) (citing *Riegel*, 552 U.S. at 321–22). If the answer is yes to both questions, the state claim is preempted. *Id.* "If, instead, the answer to the second question is no, then the state duties in such a case parallel, rather than add to, federal

requirements, and the claims are not preempted." *Id.* (citation omitted) (internal quotation marks omitted).

Even if a state-law claim is not expressly preempted, it may be impliedly preempted under § 337(a). Under the MDA, all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). "[T]he Federal Government rather than private litigants . . . are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001). To that end, the *Buckman* Court held that "state-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administrations judgment and objectives" and are impliedly preempted by the MDA. *Id.* at 350.

Ultimately, where a state-law claim for violating a state-law duty "parallels" a federal-law duty under the MDA, the MDA will not preempt the state-law claim. *Riegel*, 552 U.S. at 330. It is not enough to state that a state law parallels federal law generally. Plaintiffs must also allege a link between a product's deviation from an FDA requirement and the alleged injury. *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 598 (D.N.J. 2015); *see Simoneau v. Stryker Corp.*, No. 13-1200, 2014 WL 1289426, at *10 (D. Conn. Mar. 31, 2014) (dismissing a plaintiff's misbranding, failure to warn, and failure to report claims for failure to link her injury to a violation of an FDA requirement).

Here, it is undisputed that Mentor Breast Implants received premarket approval. (Compl. ¶ 74.) It is also undisputed that the first part of the *Riegel* preemption analysis is satisfied. (Pls.' Opp'n Br. 18.) The Court, therefore, only considers the second part of the *Riegel* test—whether Plaintiffs' state-law claims would impose requirements that are "different from or in addition to" federal safety and effectiveness requirements.

1. Strict Product Liability—Manufacturing Defect

Plaintiffs allege that "Mentor Breast Implants were manufactured in a flawed manner that violated the FDA approved design standards and specifications." (Compl. ¶ 178.) Plaintiffs allege that the breast implants she received were manufactured in a non-conforming manner because they "contained a graham-negative biofilm/endotoxin released from the surface of the textured surface which stimulates lymphocytes" (Compl. ¶ 180), and that these "bacteria stimulating lymphocytes" caused D'Addario's BIA-ALCL (*id.* ¶ 182).

Plaintiffs do not, however, allege that the FDA required the exclusion of this endotoxin. If a federal requirement is not properly identified, the Court is unable to determine whether Plaintiffs' state-law claim based upon Connecticut requirements is "different from, or in addition to," the federal ones, that relate to safety and effectiveness. *Mendez v. Shah*, 94 F. Supp. 3d 633, 639 (D.N.J. 2015). Moreover, although Plaintiffs broadly allege that Defendants "failed to adhere to [numerous] federal specifications" (*e.g.*, Compl. ¶ 184a-e), Plaintiffs fail to allege how these violations resulted in the presence of lymphocytes in her implants or any other injury. Plaintiffs' manufacturing defect claim is, accordingly, dismissed.

To the extent Plaintiffs now base their manufacturing defect claim on violations of FDA's Current Good Manufacturing Practices (*see* Pls.' Opp'n Br. 9, 17–18), these allegations are improperly pleaded in the opposition brief. "[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." *Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) (citation omitted). Because the Court grants Plaintiffs leave to amend the Complaint, Plaintiffs may further flush out this theory in an amended complaint.

2. Failure to Warn

The contours of Plaintiffs' failure-to-warn claim are unclear, as allegations that could potentially support such a claim are scattered throughout the Complaint. (*See generally* Compl.) Nonetheless, liberally construing the Complaint, the Court identifies the following two theories: (1) Defendants failed to warn "consumers, healthcare providers, the general public, and the FDA that ALCL or BIA-ALCL . . . was a potential risk of Mentor Breast Implants, and that hundreds, if not thousands, of patients had suffered negative experiences and events as a result of such known risk" (Compl. ¶ 117); and (2) Defendants failed to warn D'Addario "of the defective and unreasonably dangerous conditions of its Mentor Breast Implants that could cause serious injury or death and to timely and accurately report such adverse events to the FDA" (*id.* ¶ 179).

To the extent Plaintiffs take issue with the original warning Mentor provided to "consumers, [including D'Addario], healthcare providers, [and] the general public" (Compl. ¶ 117), this claim is preempted. A device's "proposed labeling" is reviewed during the PMA process and a manufacturer may not revise the labeling without FDA permission. *Riegel*, 552 U.S. at 318–19. "[S]tate claims based on labeling defects such as false or missing information about health risks . . . are[, therefore,] preempted in the case of Class III medical devices, because these claims necessarily impose requirements different from or additional to the FDA's requirements." *Simoneau*, 2014 WL 1289426, at *11; *see also Horn v. Thoratec Corp.*, 376 F.3d 163, 176 (3d Cir. 2004) (finding a plaintiff's state-law claims would add to the requirements imposed by the FDA on device labeling). Because Plaintiffs' claim would require Mentor to provide different warnings or instructions from those initially approved by the FDA, the claim is preempted.

To the extent Plaintiffs challenge the information Mentor provided to the FDA in its premarket approval application (Compl. ¶ 117), Plaintiffs "identif[y] no separate state law duty to

warn the FDA." *Simoneau*, 2014 WL 1289426, at *11. Moreover, such a claim fundamentally alleges fraud-on-the-FDA and would be impliedly preempted under *Buckman*. For these reasons, the Court dismisses Plaintiffs' failure-to-warn claim.

3. Negligent Misrepresentation

Plaintiffs allege that Defendants "negligently misrepresented material information regarding their product including, but not limited to, its safety." (Compl. ¶ 202.) According to Plaintiffs, "Defendants knew or should have known that their breast implants were not actually safe as they were manufactured in a defective condition." (*Id.* ¶ 203.) Plaintiffs allege that "[D'Addario] was[, therefore,] unaware and ignorant of the falsity of the statements and reasonably . . . relied upon them and believed them to be true." (*Id.* ¶ 204.)

Here, Plaintiffs' negligent misrepresentation claim fails because they wholly fail to set forth a relevant federal requirement. To the extent Plaintiffs' claim is based on defective manufacturing, the Court reiterates that Plaintiffs fail to allege a violation of a federal requirement on this basis. *See supra* Section III.B.2. Plaintiffs' negligent misrepresentation claim is dismissed.

4. Breach of Implied and Express Warranty

The Complaint alleges that "Mentor Breast Implants do not conform to . . . implied or express warranties and representations because [they] are not safe or effective for their ordinary purpose, nor are they safer or more effective than other breast implants available, [and] they were not manufactured in the specifications required by the FDA." (Compl. ¶ 220; *see also id.* ¶¶ 213–16, 221.)

Here, again, Plaintiffs' breach of warranty claim based on device safety and effectiveness fails because Plaintiffs fail to allege a violation of a federal regulation. *Supra* Section III.B.2. Furthermore, Plaintiffs' breach of warranty claim essentially challenges the safety and

effectiveness of Mentor Breast Implants, and, to find for Plaintiffs, the Court would necessarily contradict the FDA's determination of safety and effectiveness during premarket approval. Plaintiffs' breach of express and implied warranty claim is, accordingly, dismissed.

C. **Group Pleading**

Defendants argue that Plaintiffs make "the same conclusory and generic allegation against each defendant—i.e., that each defendant is responsible for 'designing, formulating, testing, packaging, labeling, producing, assembling, advertising, marketing, promoting, distributing, manufacturing, and selling'" Mentor Breast Implants. (Defs.' Moving Br. 37 (quoting Compl. ¶ 22).) According to Defendants, by "lumping" together their alleged misconduct, Plaintiffs fail to provide fair notice of the basis of their claims as against each individual defendant. (*Id.*) Defendants further argue that, although Plaintiffs allege that Johnson & Johnson and Ethicon are "agents" or "alter-egos" of Mentor or that Johnson & Johnson "controlled" Mentor, Plaintiffs fail to allege facts that support these theories. (*Id.* at 38–39.) Plaintiffs argue that they have fulfilled their duty at this pleading stage—pointing to allegations that Johnson & Johnson has owned Mentor since 2009 and that Johnson & Johnson and Ethicon admitted they are "combining forces" with Mentor. (Pls.' Opp'n Br. 37–38.)

Plaintiffs' Complaint broadly alleges Defendants' misconduct but fails to allege the conduct for which each defendant is culpable. "Courts in this district generally agree that this type of 'group pleading' does not satisfy Rule 8, because it does not place Defendants on notice of the claims against each of them." *Sheeran v. Blyth Shipholding S.A.*, No. 14-5482, 2015 WL 9048979, at *3 (D.N.J. Dec. 16, 2015). Moreover, the lack of well-pleaded facts does not allow the Court "to draw the reasonable inference that [each] defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

Plaintiffs, accordingly, have not alleged sufficient facts to identify each defendant's role with the Mentor Breast Implants. It is not enough to say that "each of the defendants is responsible for everything." *Sheeran*, 2015 WL 9048979, at *5. Nor does the *In re Riddell Concussion Reduction Litigation*, 77 F. Supp. 3d 422 (D.N.J. 2015) decision mandate a contrary conclusion. There, the plaintiffs alleged that the defendant entities took concerted action and "operat[ed] under a single brand." *Id.* at 431–32. Plaintiffs make no such allegations as to Defendants here. (*See generally* Compl.) Because Counts One through Five are directed to each of the Defendants, they are dismissed without prejudice.

D. Plaintiffs' Loss-of-Consortium Claim Fails

Because a loss of consortium claim is a derivative claim and because D'Addario fails to assert a product liability claim, Peter D'Addario's loss of consortium claim fails as a matter of law and must be dismissed. *Jacoby v. Brinckerhoff*, 735 A.2d 347, 352 (Conn. 1999) (finding a "plaintiff cannot pursue an action for loss of consortium in the absence of any basis in the record for a finding that his . . . spouse was injured as a result of her treatment by the defendant"); *see also O'Dell v. Greenwich Healthcare Servs., Inc.*, No. CV116008364S, 2013 WL 2278752, at *5 (Conn. Super. Ct. Apr. 25, 2013).

IV. CONCLUSION

For these reasons, the Court grants Defendants' Motion to Dismiss. The Complaint is dismissed without prejudice subject to the filing of an amended complaint. The Court will enter an Order consistent with this Memorandum Opinion.

MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE